Techniques in Gastrointestinal Endoscopy 16 (2014) 92–98

Contents lists available at ScienceDirect

Techniques in Gastrointestinal Endoscopy

journal homepage: www.techgiendoscopy.com/locate/tgie

The future of esophageal endoprosthetics including the use of biodegradable materials

Nandakumar Srinivasan, MD, Richard A. Kozarek, MD*

Digestive Disease Institute, Virginia Mason Medical Center, 1100 9th Ave, Seattle, Washington 98101

ARTICLE INFO

Article history:
Received 31 December 2013
Accepted 10 March 2014

Keywords:
Esophageal stent
Biodegradable stent
SEMS
Malignant dysphagia

ABSTRACT

Endoscopic esophageal stent placement is an effective palliative treatment for malignant dysphagia and complications related to esophageal malignancies. Lately, esophageal stents have also been successfully used for benign indications including anastomotic stricture, iatrogenic perforation or leak, achalasia, fistula and to stabilize patients with esophageal variceal bleeding. At present, there are a wide variety of esophageal stents available to choose from; however, an ideal esophageal stent, which is both effective and without complications, has yet to be developed. Despite the evolution in this field, challenges such as stent migration, malignant tissue ingrowth, and recurrent stricture are some of the unsolved problems. In this article, we discuss about currently available esophageal stents including biodegradable stents, various stent materials, stent designs, indications for esophageal stent placement in treating both benign and malignant esophageal diseases, clinical outcomes, complications, novel esophageal stents including drug fiber coated stents, dynamic esophageal stents, and the future direction of esophageal endoprosthetics.

1. Introduction

Before the introduction of esophageal stents, surgery was the only option for malignant esophageal stricture. In 1885, Sir Charters James Symonds, a Canadian-born surgeon, was the first to record successful placement of a short rigid esophageal tube to stent a malignant stricture. Since then, the evolution of esophageal stents has come a long way; materials have included decalcified ivory, boxwood, German silver, rigid plastic, latex, stainless steel, and now nitinol, the most commonly used stent material. Self-expandable plastic stents (SEPS) and biodegradable stents are also currently available in the global market [1].

2. Stent materials

Currently, most stents are constructed from metal. Other materials used for stents include plastic (eg, polyester) and biodegradable polymers (eg, polydioxanone) (Table). Wallstent, the first commercially produced self-expandable metal stent (SEMS), was made of stainless steel and was manufactured by Schneider Inc, Switzerland. In 1993, the seminal randomized controlled trial using an uncovered Wallstent by Knyrim et al [2] led to replacement of rigid prostheses with SEMS for the palliation of malignant dysphagia. Some of the disadvantages of this first SEMS included relatively short lengths, tumor ingrowth, absence of a proximal flare, and exposed wire filaments in the ends that caused mucosal injury and potential damage to the endoscope. An American model of the Wallstent was designed with a partial silicone cover and tulip-shaped proximal end to address the aforementioned problems. However, this prototype stent had a bulky delivery system making it difficult to deliver [3]. Later, a partially covered version of this stent was made and found to be effective.

Ultraflex stent, made by Boston Scientific (Natick, MA), was the first stent made of nitinol (NiTiNoL—Nickel Titanium Naval Ordnance Laboratory), a shape-retaining nickel and titanium alloy. Kauffman and Mayo [4] have described 2 unusual properties, the shape memory and the super elasticity (20-30 times more than most other metals) of the nitinol. By heating it to approximately 500°C, a specified shape can be imprinted on the nitinol structure by creating an ordered (austenite) atomic structure within the crystalline matrix of the metal. After cooling, the atomic structure subluxes to a more complex (martensite) arrangement, and this metal can be easily deformed. On rewarming, the atoms attempt to regain the imprinted (austenite) configuration, and therefore the structure regains the original shape. For medical devices, rewarming occurs at the body temperature.

The first-generation Ultraflex stent was uncovered and encountered the same problems such as tumor ingrowth as the other

Dr. Richard Kozarek has been a consultant for TaeWoong.

* Corresponding author.
E-mail address: Richard.Kozarek@vmmc.org (R.A. Kozarek).

http://dx.doi.org/10.1016/j.tgie.2014.03.001
0049-0172/

Table
Esophageal stents available in the United States and Europe.

Manufacturer and stent name	Types FC or PC or NC	Material	Covered	Length, cm	Stent diameter shaft/flare, mm	Introducer size, mm	Antireflux valve	FDA approved
Boston Scientific								
Polyflex	FC	Polyester	Silicone	9/12/15	16/20; 18/23; 21/28	12 and 14	No	Yes
Ultraflex	PC or NC	Nitinol	Polyurethane	10/12/15	18/23; 23/28	6	No	Yes
WallFlex	FC or PC	Nitinol	Polyurethane	10/12/15	18/23; 18/25; 23/28	6	No	Yes
Cook Medical								
Esophageal Z	FC	Stainless steel	Polyurethane	8/10/12/14	18/25		Yes	Yes
Evolution	PC	Nitinol	Silicone	8/10/12.5/15	20/25		No	Yes
Evolution	FC	Nitinol	Silicone	8/10/12	18/23; 20/25		No	Yes
TaeWoong Medical								
Niti-S	PC	Nitinol	Polyurethane	8/10/12/15	16/24	5.8 and 6.5	Yes or no	Yes
Niti-S	FC	Nitinol	Polyurethane	8/10/12/15	18/26; 20/28	5.8 and 6.5		Yes
Merit Endotek								
Alimaxx-ES	FC	Nitinol	Polyurethane	7/10/12	12/14/16/18/22	5.3	No	Yes
Endochoice								
Bonastent	PC or FC	Nitinol	Silicone	6/8/10/12/15	18/23; 20/25; 22/27	6	Yes or no	Yes
ELLA-CS								
SX-ELLA	FC	Nitinol	Silicone	8.5/11/13.5/15	20/25	4.7 and 5.9	Yes or no	No
FerX-ELLA	PC or FC	Stainless steel	Polyethylene	9/10.5/12/13.5 15/16.5/19.5/21	20/36; 18/23	5.9	Yes or no	No
SX-ELLA-BD	BD	Polydioxane		6/8/10/13.5	20/25; 23/28; 25/31	5.9	No	No
M.I.Tech								
Choo	PC or FC	Nitinol	Polyurethane	8-17	18/24; 20/26		Yes	No
Hanaro	FC	Nitinol	Silicone	8-17	18/24	6 and 8	Yes or no	No
Hanaro benign BS	FC	Nitinol	Silicone	8-12	20/26; 22/28	6 and 8	No	No

Abbreviations: NC, no cover; PC, partially covered; FC, fully covered; FDA—US Food and Drug Administration.

uncovered SEMS [5]. Subsequently, a partially covered version of this stent was developed and is still used in many parts of the world. A disadvantage of this stent is a high degree of foreshortening (25%-40%) at the time of deployment. There were also reports of poor stent expansion requiring dilation in up to one-third of the patients [6].

SEPS (Polyflex, Boston Scientific), which originally were less expensive than metal stents, are also currently available. This stent has a braided polyester skeleton covered with silicone on the inside. It has a high radial force and a rough outer texture. The disadvantages are the size of the delivery system (as large as 42 F), lack of radiopacity except for 3 bands of radiopaque markers, and relatively high complication rates associated with their use [7,8], which includes migration rate as high as 63% [9].

Although the use of biodegradable stents in the gastrointestinal tract goes back as far as 1997 [10], at present, only 1 is commercially available (Ella-BD, Ella-CS, Hradec Kralove, Czech Republic). This stent is made of a complex polymer (polydioxanone), which disintegrates through hydrolysis over 3-4 months. This process is accelerated within an acidic environment [11]. The disadvantages are significant stent shortening, radiolucency except for added markers, and reduced elasticity. Because of the reduced elasticity, these stents are supplied outside the delivery system and need to be loaded through a funnel before its use. Presently, biodegradable stents are only approved for the treatment of benign esophageal strictures [12].

Currently, with the development of SEPS and SEMS, esophageal stent placement for malignant stricture or benign conditions including iatrogenic perforations and leaks, tracheoesophageal fistulae, and refractory strictures caused by peptic ulcer, radiation, or surgical anastomosis has become safer, less invasive, and cost-effective [13,14].

3. Types of stents

Esophageal stents are available in 3 fundamental designs: fully covered, partially covered, and uncovered. Fully covered stents are often more prone to stent migration, whereas partially covered SEMS have a small portion of exposed bare metal in both proximal and distal ends to allow embedding into the esophageal wall, which helps to decrease stent migration. A variety of covering materials have been developed, but most commonly, polytetrafluoroethylene is used for the covered stents [15].

4. Designs of SEMS

There are a variety of different SEMS designs available in the market. Each design has its own advantages and disadvantages.

4.1. Segmental stents

Individual cylindrical metal baskets are connected to each other to form a semirigid tube. The Gianturco-Rösch Z-stent (Cook Medical, Bloomington) was one of the earliest designs consisting of multiple stainless steel segments connected by sutures and covered by polyurethane. This stent has low elasticity and needs to be loaded into a delivery sheath before use, has high straightening force, and at times leads to pressure necrosis and perforation of esophageal wall [16].

The second-generation stainless steel esophageal stents (Boubella, Ella-CS, Hradec Kralove, Czech Republic) (Figure 1) and the first stents based on nitinol baskets (Choo or Do Stent, M.I.Tech, Seoul, South Korea) had improved flexibility, but owing to the rigidity of individual segments, tended to buckle rather than bend [17].